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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,430	01/11/2002	Thomas D. Driskell	DI-00-01	9948

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EXAMINER	
MCDONALD, RODNEY GLENN	

ART UNIT	PAPER NUMBER
1753	6

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

a060

Office Action Summary	Application No.	Applicant(s)
	10/045,430	DRISKELL ET AL.
	Examin r	Art Unit
	Rodney G. McDonald	1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deutchman et al. (U.S. Pat. 4,992,298) in view of Cotell et al. (U.S. Pat. 5,242,706).

Deutchman et al. teach a dual ion beam ballistic alloying process for forming a film onto a substrate which comprises the steps of: (a) cleaning the surface of the substrate with a first energy beam of inert atoms; (b) *depositing a layer of a desired non-hydrocarbon substance on the substrate with a low energy, sputtered atomic beam; (c) simultaneously exposing the substrate to said first energy beam of inert atoms with a high energy to grow a ballistically alloyed layer having a thickness of about 10-2000 Angstroms; and reducing the energy level of the first, high energy beam to cause the growth of the layer of said substance on said substrate to a final desired thickness.* **(See abstract)**

The invention comprises, in a first aspect, a low temperature process for forming a stress reduced film adhered to a substrate in an evacuated atmosphere, ***comprising depositing a layer of a desired non-hydrocarbon substance on the substrate with a low energy, sputtered atomic beam; simultaneously exposing the substrate to a first, high energy beam of inert atoms to grow a ballistically alloyed layer of an initial desired thickness; reducing the first, high energy beam to a second, substantially less high energy beam and continuing the growth of the layer to attain a film of a final desired thickness on the surface of the substrate.*** (Column 2 lines 13-24)

Ion beam source 26, upon completion of precleaning of substrate 16, is then used to produce ion beam 28 which is an inert gas such as argon, although other gases such as neon, krypton, xenon and the like can also be utilized. ***The ion beam 28 strikes an ultra high purity sputtering target 31, typically made of 99.999% pure graphite or, if desired, another desired target material such as boron, silicon, a metal or a composite material such as a refractory carbide, nitride, oxide or the like.*** This beam 28 has an energy level of about 1200 eV and a

current density ranging from about 0.1-50.0 ma/cm^2. After beam 28 strikes target 31 it produces a sputtered, low energy atomic beam 32 comprised of the target atoms, which typically have an energy level ranging from about 1-50 eV, most preferably about 1-10 eV for carbon or similar target materials. ***The sputtered beam 32 strikes the substrate 16 and forms a thin layer of the sputtered pure atomic materials on the surface of the substrate.*** It is essential in the production of diamond films that the sputtered material cannot be a hydrocarbonaceous substance since it is imperative that the deposited diamond films be kept completely hydrogen free, and thereby are greatly reduced in internal stresses. (Column 3 lines 49-68; Column 4 lines 1-3)

Simultaneously with the aforementioned bombardment of the substrate 16 with beam 32, ion beam source 20 generates a different beam 18, which is a high energy beam of inert atoms, i.e., argon, neon, krypton and xenon, having energies ranging from about 0.5-100 KeV, preferably 0.5-5.0 KeV. ***This high energy beam strikes the substrate 16 concurrently with the initial deposition of the sputtered carbon or other low energy atoms present in beam 32 and bombards the substrate 16 surface until a ballistically alloyed layer ranging in thickness from about 10-2000 Angstroms preferably about 10-20 Angstroms has been bonded onto the substrate. The term "ballistically alloyed" describes a process of firmly adhering a layer onto a substrate by bombardment of the substrate surface with high energy particles that become physically mixed and/or chemically bonded within the substrate surface.*** The resulting effect is to grow a surface layer having a thickness which extends not only above the immediate substrate surface but also extends into the substrate surface a short distance in a manner similar to a diffusion bonded layer. Thus, the net effect of the high energy bombardment while simultaneously depositing a low energy sputtered film is to create a ballistically bonded, thin, preferably hydrogen-free, reduced in internal stress, amorphous, crystalline or polycrystalline layer of a pure substance firmly alloyed into the substrate. ***The ballistic alloying occurs in a thin, e.g., from 10-2000 Angstroms and preferably 10 to 20 Angstroms boundary zone in***

which the sputtered layer has become physically mixed and/or chemically bonded with the substrate to produce a strong, effective bond. (Column 4 lines 4-34)

Upon completion of the thin bonding layer on the substrate 16, beam 18 is transformed from a high energy beam into a substantially lower but still high energy beam 18 and the two beam deposition process is continued until the desired coated thickness upon the substrate is attained. (Column 4 lines 35-40)

The second beam 18 which continues the high energy bombardment of the deposited film on the substrate surface 16 after the aforementioned boundary layer has been formed is preferably the same ion beam of inert atoms which were utilized in the high energy first beam. Typically, the lower high energy beam 18 has an average energy from about 100-500 eV, preferably from about 150-200 eV. ***As earlier mentioned, this beam replaces the high energy beam 18 when the deposited film attains a thickness which can typically range from about 10 Angstroms or slightly thicker and assists in growing the remainder of the sputtered deposited film onto the substrate.*** (Column 4 lines 41-53)

The resultant coated films range in thickness typically from about 100-200,000 Angstroms, and for most applications from about 1000-20,000 Angstroms. Although the process is particularly suitable for forming a variety of desired diamond and diamond-like films upon the surface of the substrate, a wide variety of other hard films such as nitrides, borides, carbides, oxides and the like can also be so deposited onto a desired substrate. It is, of course, apparent to one skilled in the art how changing the particular sputtered materials and/or reactive or inert gases, as well as the various energy levels of the beams, can make the resulting films morphologies different. (Column 4 lines 54-65)

Additionally, the process is suitable for treating an extremely wide variety of substrates, such as metals, plastics, glasses, ceramics and the like, whereas most other prior art systems are

quite limited with respect to the substrates which can be treated. (Column 4 lines 66-68; Column 5 lines 1-2)

The differences between Deutchman et al. and the present claims is that depositing as the desired material an inorganic material containing calcium phosphate such as hydroxylapatite is not discussed, the substrate being of C.P. titanium or titanium alloy is not discussed, the substrate being a resin is not discussed and the article such as a dental implant and an orthopedic implant made by the method is not discussed.

Cotell et al. teach utilizing as a substrate a medical, dental or orthopedic implant for supporting films of hydroxylapatite which contains calcium phosphate. (Column 1 lines 8-20; Column 3 lines 20-31) The substrate is preferably corrosion-resistant an it may generally comprise any suitable material, e.g. metal, alloy, ceramic and/or polymer material in any suitable shape. Preferred substrates include Ti alloys, PVC, synthetic resins, rubbers etc. (Column 3 lines 62-68; Column 4 line 1)

Cotell et al. teach that during deposition a suitable ion source can be used to pre-clean substrates in-situ, to improve adhesion between the deposited film of biocompatible material and the substrate and/or to densify the biocompatible material as it is being deposited. (Column 5 lines 59-63) By utilizing the ion beam one can control the porosity of the deposited film and enhance the adhesion of the film to the substrate. (Column 6 lines 35-37)

The motivation for utilizing an inorganic material containing calcium phosphate such as hydroxylapatite is that it allows for production of a film that is biocompatible. (Column 3 lines 20-27) The motivation for utilizing a substrate of titanium alloy or resin is that it allows for providing a corrosion resistance. (Column 3 line 62) The motivation for utilizing a substrate of in the form of a dental implant and an orthopedic implant is that it allows for production of articles for short- or long-term contact with human or animal tissue. (Column 1 lines 8-19)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Deutchman et al. by depositing as the desired material an inorganic material containing calcium phosphate such as hydroxylapatite, by utilizing a substrate of C.P. titanium, titanium alloy or a resin and utilizing as the substrate an article such as a dental implant or an orthopedic implant as taught by Cotell et al. because it allows for allows for production of a film that is biocompatible, allows for providing corrosion resistance and allows for production of articles for short- or long-term contact with human or animal tissue.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deutchman et al. (U.S. Pat. 4,992,298) in view of Imai et al. (Japan 09-301797).

Deutchman et al. is discussed above and all is as applies above. (See Deutchman et al. discussed above)

The differences between Deutchman et al. and the present claims is that depositing as the desired material an inorganic material containing calcium phosphate such as hydroxylapatite is not discussed, the substrate being of C.P. titanium or titanium alloy is not discussed, the substrate being a resin is not discussed and the article such as a dental implant and an orthopedic implant made by the method is not discussed.

As to a titanium alloy or resin substrate being utilizing since Deutchman et al. teach metals, plastics, glasses and ceramics these substrate materials encompass the material of titanium alloys or resins. (See Deutchman et al. discussed above)

Imai et al. teach that to coat an article to be coated with a film such as a living body-applicable article with a crystallized ***calcium phosphate compd. film*** with good adhesion by forming a calcium phosphate compd. film on the article by using vapor deposition and ion irradiation at the same time and then bringing the film into contact with a pseudbody fluid. (See Abstract)

Imai et al. teach that vapor deposition (a sputtering target 31 and a sputtering ion source 32) and ion irradiation (assist ion source 4) are jointly used to form ***a calcium phosphate compd. film*** on an article S. The film is then brought into contact with a pseud body fluid to crystallize ***the calcium phosphate compd. in the film***. Ion-beam sputter vapor deposition is preferable as the vapor deposition. Meanwhile, a calcium phosphate compd. with the ratio of P to Ca controlled to 0.8-1.2 is preferably used. A tissue culture soln. contg. Ca and P can be used as the pseud body fluid. (See Abstract)

Imai et al. teach that substrates to be utilizing in living tissue include ***dental implants, artificial joints (i.e. orthopedic implant), etc.*** (See Computer translation page 1)

The inorganic compound can include ***hydroxyapatite***. (See Computer translation page 2)

The motivation for depositing as the desired material an inorganic material containing calcium phosphate such as hydroxylapatite, utilizing a substrate of C.P. titanium or titanium alloy, utilizing a substrate of a resin and utilizing an article such as a dental implant and an orthopedic implant is that it allows the article to be utilized in the living body. (See Abstract)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Deutchman et al. by utilizing as the desired material an inorganic material containing calcium phosphate such as hydroxylapatite, utilizing a substrate of C.P. titanium or titanium alloy, utilizing a substrate of a resin and utilizing an article such as a dental implant and an orthopedic implant as taught by Imai et al. because it allows the article to be utilized in the living body.

Response to Arguments

Applicant's arguments filed 8-19-03 have been fully considered but they are not persuasive.

The 35 U.S.C. 112 2nd paragraph rejection has been overcome.

RESPONSE TO 35 U.S.C. 103 ARGUMENTS OF CLAIMS 1-12 AS OBVIOUS OVER DEUTCHMAN ET AL. IN VIEW OF COTELL ET AL.:

In response to Applicant's argument that Duetchman et al. employ no heating or suggest no heating of the substrate whereas Cotell et al. require heating the substrate, it is argued that Duetchman et al. process could employ heating if desired. Applicant's claims require only that a relatively "low" temperature be employed to deposit the material. "Low" temperatures could employ heating. (See Cotell and Duetchman et al. discussed above)

In response to the argument that Cotell et al. do not teach or suggest the use of any ion assisted coating process to coat implantable articles with biocompatible materials, it is argued that the primary reference to Duetchman et al. was relied upon to teach the use of ion assist to coat implantable articles. Cotell et al. was relied upon to teach the materials utilized in Applicant's process. (See Deutchman and Cotell discussed above)

RESPONSE TO THE 35 U.S.C. 103 ARGUMENTS OF CLAIMS 1-12 AS OBVIOUS OVER DEUTCHMAN ET AL. IN VIEW OF IMAI ET AL.:

In response to the argument that there is no suggestion in Imai et al. for one skilled in the art to use the Deutchman et al. process which involves depositing a layer on a substrate by sputtering a beam of inert ions at a selected energy rate to grow a ballistically alloyed layer and then to continue the another beam at a reduced energy level to cause the growth of a film on the substrate of a final desired thickness as a pretreatment step for an immersion process to grow crystalline calcium phosphate, it is argued that Deutchman et al. teach Applicant's process and that Imai et al. suggest that the material deposited by Applicant can be deposited by utilizing an ion beam and ion beam sputtering. (See Deutchman et al. and Imai discussed above)

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney G. McDonald whose telephone number is 703-308-3807. The examiner can normally be reached on M- Th with Every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 703-308-3322. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Rodney G. McDonald
Primary Examiner
Art Unit 1753

RM
November 24, 2003